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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

TSRI 829.0

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Application Number

10/090,183

Filed

03/02/2002

First Named Inventor

Ralph A. Reisfeld

Art Unit

1636

Examiner

Michael D. Burkhart

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

applicant/inventor.

assignee of record of the entire interest.

See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)

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Registration number if acting under 37 CFR 1.34

August 24, 2005

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

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Pre-Appeal Brief Request for Review

A. The examiner maintains that the specification teachings, taken together with presented actual data obtained using an animal model, do not satisfy the enablement requirement of 35 U.S.C. 112, first paragraph.

B. Remarks.

The Examiner himself has recognized at page 4 of the Office Action dated 26 August 2004, and at page 5 of the present Office Action, the level of skill in this particular field of art is high. Thus, the working examples, data, and teachings contained in the specification provide more than adequate guidance to those skilled in the art to practice the claimed invention.

In particular, ample experimental data have been provided in the specification. See, for example, the description at pages 15-21 under the heading Materials, Methods and Examples, and FIGURES 7-11, inclusive, and the explicit general teachings in the specification at page 7, l. 30 to page 15, l. 8. In addition, mouse Flk-1 (SEQ ID NO: 6) shares an approximately 85 percent homology with human KDR and plays an analogous role in mouse physiology to that of KDR in humans. Accordingly, the mouse model is indeed an appropriate model in the present case.

Applicants' position is further supported by Marshall et al., *J. Clin. Oncol.* 23(4):720-31 (2005), and Schlam et al., *Dev. Biol. (Basel)* 116:27-47 (2004), copies enclosed for convenience and ready reference. Marshall et al. report on the use of recombinant vaccines in human patients to generate significant immune responses. Schlam et al. report on pre-clinical as well as clinical studies using recombinant vaccines. It must also be noted that Schlam et al. teach the suitability of the mouse model for such studies, and that the results of such studies can be extrapolated to human patients.

Garmory et al. do not support the Examiner's non-enablement argument. The following passage from Garmory et al. at p. 348 must also be considered:

The future for *Salmonella* vaccines looks very promising. A number of well-tolerated attenuated *S. enterica* var. Typhi strains have been shown to be immunogenic in clinical trials.

These are clearly promising candidate typhoid vaccines. In addition, *Salmonella* vaccines have been shown to protect against a broad range of pathogens in animal models and preliminary results from clinical trials demonstrate that protective immunity against heterologous antigens is achievable. In addition, *Salmonella* vaccines have been successfully used to induce antitumour immunity [138,172,173]. Various problems have been encountered, particularly in the development of bivalent *Salmonella* vaccines, but numerous solutions have been obtained already and other problems are likely to be addressed in a similar manner.

The foregoing clearly militates against the Examiner's position. Garmory et al. clearly state that *Salmonella* vaccines have been used successfully to induce antitumor immunity.

Restifo et al. arguably illustrates the state of the art as of Year 2000, not as of the 2 March 2002 filing date of the present application and cannot be used to show state of the art at the time of filing.

The Gura reference is inapposite as well. Gura alleges that the known systems for identification of anticancer drugs are faulty, and that mouse xenograft models may not be reliable. The present claims, however, are not directed to anticancer drugs or therapy in general but to specific DNA vaccines. A vaccine is not a drug.

The discussion in Steinman et al. about promising immunotherapy discoveries in mice that failed to translate in humans is but an undated historical account that sheds no light whatsoever on the enablement issues in this particular application.

The Examiner's unsupported contention that the state of the art "would require that undue and excessive experimentation would have to be conducted by the skilled artisan to practice the present invention" cannot support a rejection. In essence, the Examiner seeks to augment his position not by evidence but merely by his own allegations. The unsupported opinion of the Examiner as to what experimentation would have been required in March 2002 by one of ordinary skill in the art is of no import with regard to the issue at hand.

Early passing of this application to issue is solicited.